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IN THE

Supreme Court of the United States

CHARLES R. RIEGEL AND DONNA S. RIEGEL,

Petitioners,

v.

MEDTRONIC, INC..

Respondent.

On Writ Of Certiorari to the United States Courts of Appeals for the Second Circuit

AMICUS CURIAE BRIEF OF THE AMERICAN ASSOCIATION FOR JUSTICE AND PUBLIC JUSTICE IN SUPPORT OF PETITIONERS

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IDENTITY AND INTEREST OF *AMICI CURIAE*

The American Association for Justice ["AAJ"], formerly the Association of Trial Lawyers of America, and Public Justice respectfully submit this brief as *amici curiae*. The parties have filed letters of consent to the filing of amicus briefs.[1]

AAJ is a voluntary national bar association whose approximately 52,000 trial lawyer members primarily represent individual plaintiffs in civil suits and personal injury actions, including plaintiffs injured by unsafe medical devices. Throughout its 40-year history, the association has championed the fundamental right of every American to legal recourse for redress of wrongful injury. AAJ views the lower court's decision in this case as an unwarranted expansion of the preemption doctrine that undermines that fundamental right.

Public Justice is a national public interest law firm dedicated to pursuing justice for the victims of corporate and governmental abuses. Through involvement in precedent-setting and socially significant litigation, Public Justice seeks to ensure that tort law fully serves its dual purposes – compensating those injured by wrongful conduct and deterring similar conduct in the future. Public Justice is gravely concerned that, if the tort system is closed to innocent victims of defective medical devices through application of the preemption doctrine in this case, neither of these purposes will be served.

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[1] Pursuant to Rule 37.6, Amici disclose that no counsel for a party authored any part of this brief, nor did any person or entity other than Amici Curiae, their members, or counsel make a monetary contribution to its preparation.

SUMMARY OF THE ARGUMENT

1. The court below erred in holding that the Medical Device Amendments of 1976 expressly preempt not only state administrative regulation of devices, but also state product liability damage lawsuits.

Congress enacted the MDA to expand the authority of the FDA to keep unsafe medical devices off the market before they could cause injury. Lawmakers were responding to the harms caused by the Dalkon Shield and other unsafe medical devices that had resulted in numerous lawsuits. Congress did not respond by protecting manufacturers from liability for such injuries. In fact, there is no indication in the legislative history that Congress sought to eliminate state-law remedies for injury. Rather, Congress saw this litigation as symptomatic of a regulatory shortfall. Its response was to fill this gap by enacting *additional* tools for protecting the public.

The most important of this Court's canons of construction regarding preemption provisions is the presumption against preemption. Congress must be presumed to have intended to leave state law remedies in place in the absence of clear and unambiguous intent to the contrary. The court below, however, construed § 360k through preemption-colored glasses, holding that a State "requirement" *should* include common-law actions simply because it *could* be so construed.

2. The court below erred in holding that plaintiffs' product liability action, if successful, would impose a state requirement different from the federal requirement under the MDA. Although preemption of state requirements may in some circumstances encompass common law duties, Congress narrowly

wrote the MDA to preempt only state requirements "with respect to a device." Plaintiffs' causes of action in this case are based on the duties imposed on all manufacturers to exercise due care under the circumstances in designing products and warning of their dangers. These general common law duties are not requirements with respect to medical devices.

Nor are plaintiffs' causes of action preempted on the theory that a jury verdict would establish a requirement with respect to the specific device in this case. A jury is not a "State or political subdivision of a State." Moreover, a jury verdict in plaintiff's favor imposes no requirement upon the defendant apart from the obligation to pay compensation. Although a verdict may motivate the defendant to change a product to avoid future liability, such a financial incentive does not amount to a "requirement." The Supremacy Clause and the preemption doctrine are not concerned with speculative influences on private decisionmaking.

3. The court below erred in basing its holding on the notion that Congress intended to rely solely upon FDA regulation to ensure the safety of the most potentially dangerous medical devices – those subject to PMA approval.

For nearly a century, America has relied on a two-pronged approach to consumer product safety. Government regulation overrides the marketplace and imposes safety directly by decree. Product liability, on the other hand, operates indirectly through the marketplace. By requiring the manufacturer to internalize the costs of injury as part of the price of the product, the market creates a financial incentive for manufacturers to make their products reasonably safe. These two approaches to

product safety are radically different, and this Court has consistently held that Congress can intend to preempt state regulatory requirements while leaving in place the indirect effects of tort awards.

Indeed, as Congress was undoubtedly aware, courts have traditionally viewed regulation and liability as complementary approaches to product safety. Courts have harmonized those approaches in the well-settled rule that compliance with regulatory requirements is evidence of, but not conclusive of, due care.

There is no evidence that Congress intended to rely exclusively on FDA regulation to ensure the safety of potentially dangerous medical devices. Congress was well aware of the limitations on the agency's abilities to protect the public. Moreover, Congress would not have eliminated without comment the consumer's right to seek legal remedy for wrongful injury. This Court has recognized that right as fundamental for over two hundred years. Congress should not be presumed to have cast it aside without clear indication that it intended to take so drastic a step.

ARGUMENT

I. IN ENACTING THE MEDICAL DEVICE AMENDMENTS, CONGRESS DID NOT CLEARLY AND UNAMBIGUOUSLY PREEMPT PRIVATE CAUSES OF ACTION FOR INJURY CAUSED BY UNSAFE DEVICES.

The court below erred in ruling that, because an express preemption of state "requirements" *could* encompass common law remedies, the MDA *should*

be so interpreted, disregarding the strong presumption that Congress intended to leave the matter of remedy for wrongful injury to the States.

A. Congress Enacted the Medical Device Amendments To Protect Consumers By Expanding the FDA's Pre-Marketing Authority, Not To Protect Device Makers from Post-Marketing Liability.

Amici address this Court on an important and dispositive issue in this case: Whether an individual's product liability claim is a state "requirement" that is expressly preempted by the Medical Device Amendments of 1976, 21 U.S.C. § 360k. The lower court held that § 360k(a) preempts not only the positive law of a state – legislative and administrative regulation – but also an individual's private cause of action for personal injury. *Riegel v. Medtronic, Inc.*, 451 F.3d 104, 120-23 (2d Cir. 2006).

In 1976, Congress took a dramatic step to protect the health and safety of Americans. Congress recognized that new and sophisticated medical devices, particularly those designed to be placed inside the body, pose a serious risk of harm to consumers. S. Rep. No. 94-33, at 5 (1976), *reprinted in* 1976 U.S. Code & Admin. News 1070, 1074. Injuries to women caused by the Dalkon Shield IUD, for example, resulted in more than 500 lawsuits seeking compensation. H.R. Rep. No. 853, at 8 (1976). In 1976, Dalkon Shield lawsuits were the largest category of product liability actions pending in federal courts, outnumbering even asbestos cases. U.S. General Accounting Office, Product Liability: Extent of "Litigation Explosion" in Federal Courts Questioned, HRD-88-36BR (Jan. 1988) at 22.

Congress responded to the numerous injuries linked to harmful medical devices not by declaring a need to protect device makers from lawsuits, but by creating *additional* tools to prevent future tragedies. Indeed, "the entire legislative history reveals no mention of preempting state common law tort claims." Robert S. Adler & Richard A. Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 Mo. L. Rev. 895, 923 n.128 (1994). It was private litigation, not the efforts of the Food and Drug Administration, that brought the problems of unsafe devices to lawmakers' attention. *Id.* at 944-45.

Congress saw these injury lawsuits as symptomatic of a serious regulatory shortfall. The FDA had acted swiftly to remove the Dalkon Shield from the market, but it was too late for thousands of women who suffered toxic shock, infertility, and pelvic infections.[2] The question that concerned Congress was not whether the manufacturers should be held liable for injuries, but rather why the FDA could not keep unsafe devices off the market in the first place. Of particular concern were the Dalkon Shield, catheters, artificial heart valves, defibrillators, and pacemakers. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476 (1996). These devices "became the symbols that spurred Congressional action to protect the public from the harmful effects of a largely unregulated device industry." *Ministry of Health v. Shiley, Inc.*, 858 F. Supp. 1426, 1434 (C.D.

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[2] The story of the Dalkon Shield scandal is told in *In re A.H. Robins Co.*, 880 F.2d 709, 710-12 (4th Cir.), *cert. denied*, 493 U.S. 959 (1989); and in Richard B. Sobol, BENDING THE LAW: THE STORY OF THE DALKON SHIELD BANKRUPTCY (1991).

Cal. 1994). Witness after witness in congressional hearings blamed the numerous injuries and deaths caused by medical devices on the FDA's inability to assure their safety prior to marketing. *See* S. Rep. No. 94-33, at 7-10 (1976), *reprinted in* 1976 U.S. Code & Admin. News 1070, 1076-79.

At that time, the FDA possessed no specific authority to regulate the entry of medical devices into the market, as it possessed with respect to drugs. H.R. Rep. No. 853, at 2-3 (1976). The agency had authority to monitor and regulate the sale of medical devices. *See* 21 U.S.C. § 331 (1994) (prohibiting commerce in adulterated or misbranded medical devices). But its enforcement powers were limited to recalls and other post-marketing actions.

To fill this gap, Congress passed the Medical Device Amendments ["MDA"], which created a regulatory structure for the FDA to require that medical devices be shown to be safe and effective prior to entering the market. Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified at 21 U.S.C. § 360c et seq.). The statute's overriding purpose was to "provide for the safety and effectiveness of medical devices intended for human use." 90 Stat. 539 (preamble).

Congress included in the MDA an express preemption provision:

> (a) General rule. Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –
>
> (1) which is different from or in addition to, any requirement applicable under this Act to a device, and

> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.

21 U.S.C. § 360k(a).

The question before the Court is whether Congress intended this provision to prevent future victims from bringing state-law tort actions for harms caused by unsafe medical devices that have managed to reach the marketplace. The answer is clearly "No."

B. The Court Below Failed to Interpret the MDA's Express Preemption Provision Consistent With the Strong Presumption Against Preemption of State Law Remedies for Personal Injury.

This Court's "canons of construction" for interpreting express preemption provisions are well-known. The intent of Congress provides the "touchstone" in matters of federal preemption of state law. *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992); *Lohr*, *supra*, 518 U.S. at 485. Courts ascertain congressional intent from the plain wording of a preemption provision, *Cipollone*, 505 U.S. at 523-24; *Lohr*, 518 U.S. at 484, as well as from "both textual and legislative context" of the statute. *Cipollone*, 505 U.S. at 519 n.16 (1992); *Lohr*, 518 U.S. at 489-90.

Most importantly, courts must assume that "the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Cipollone*, 505 U.S. at 518; *Lohr*, 518 U.S. at 485. This presumption is even stronger where, as here,

preemption would leave injured individuals without any legal remedy for wrongful injury. *Lohr*, at 487 (plurality), citing *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984). If congressional intent to eliminate state tort remedies is not unambiguously clear, it is not the role of the courts to supply it.[3]

The court below did not reject the presumption against preemption, but it nevertheless read the statutory language through preemption-colored lenses. It reasoned that, because "a state 'requirement,' for purposes of the MDA, *could* stem from state common-law actions," then "Section 360k(a)'s reference to state 'requirements' *should* be interpreted to encompass state common law actions." 451 F.3d at 116 & 123 (emphasis added).

The presumption applied by the lower court was clearly one that *favored* preemption. In fact, the court turned the presumption completely upside down, shifting the onus to Congress to "amend Section 360k(a) to make clear that its reference to state 'requirements' does not include state tort actions." 451 F.3d at 124.

This approach flies in the face of this Court's repeated teachings that congressional silence is not a sufficient basis for extending the scope of express preemption beyond state positive law to encompass common-law remedies. *See, e.g., Sprietsma v. Mercury Marine*, 537 U.S. 51, 69 (2002) (provision of the Federal Boat Safety Act, 46 U.S.C. § 4306,

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[3] "When judges preempt state laws in the absence of explicit congressional guidance, they in effect assume a legislative role without accepting legislative responsibility." Kenneth Starr, et al., The Law of Preemption: A Report of the Appellate Judges Conference of the American Bar Association 48 (1991).

preempting state laws, regulations, or standards "imposing a requirement," does not also preempt tort claims where the statute does not convey Congress's "clear and manifest intent to sweep away state common law."); *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 452 n.26 (2005) (in Federal Insecticide, Fungicide, and Rodenticide Act, express preemption of state "requirements" does not include tort remedies where "the lengthy legislative history is barren of any indication that Congress meant to abrogate most of the common-law duties long owed by pesticide manufacturers."); *Geier v. American Honda Motor Co., Inc.*, 529 U.S. 861, 868 (2000) (preemption of state "standards" does not include tort actions where the Court "found no convincing indication that Congress wanted to pre-empt, not only state statutes and regulations, but also common-law tort actions.").

II. A State Does Not Establish a Requirement With Respect To A Device When A Jury Returns A Verdict For The Plaintiff In A Product Liability Action.

The court below erred in holding that a verdict in plaintiff's favor in a product liability case results in a requirement established by the State.

A. General Common-Law Duties Establish No Requirement "With Respect To A Device."

This Court has indicated that express preemption of state "requirements" could, in some circumstances, embrace general common law duties. *Cipollone*, 505 U.S. at 522; *Bates*, 544 U.S. at 443. However, Congress wrote 21 U.S.C. § 360k(a)

narrowly. Its preemptive scope includes only a requirement "with respect to a device." A majority of this Court has held that the MDA's preemption of any state "requirement" does not include "general state common-law requirements," such as "the general duty of every manufacturer to use due care to avoid foreseeable dangers in its products." *Lohr*, 518 U.S. at 501 (Part V).

Plaintiffs in this case have alleged negligence in design, negligent failure to warn, strict liability, and breach of implied warranty. Such general duties, as the Court pointed out, "were not specifically developed "with respect to" medical devices." *Id.*

Additionally, these duties merely create a financial incentive for a manufacturer to exercise due care under the circumstances. The focus of the inquiry is whether the manufacturer acted reasonably in marketing a product with a known and preventable risk of injury. David G. Owen, *Proving Negligence in Modern Products Liability Litigation*, 36 Ariz. St. L.J. 1003, 1003 (2004). Applicable New York product liability law is no different:

> New York courts generally consider design defect and negligence claims "functionally synonymous," . . . Ultimately, the inquiry in a design defect case 'requires a fact finder to make a judgment about the manufacturer's judgment' in choosing to design a product in a certain way.

Barban v. Rheem Textile Sys., Inc., 2005 WL 387660, at *7 & *8 (E.D.N.Y. 2005) (citations omitted).

Thus, these common law duties merely relate to a manufacturer's *conduct*; they do not impose any specific requirement with respect to the design of the product itself.

B. A Verdict In Plaintiff's Favor Does Not Establish A "Requirement" With Respect to a Device.

The court below, responding to plaintiff's argument that § 360k does not encompass general common law duties, shifted its focus to jury *verdicts*. The court stated that, "a verdict [in the Riegels' favor] would clearly differ from the FDA's PMA approval of the device." *Riegel v. Medtronic, Inc.*, 451 F.3d 104, 114 (2d Cir. 2006). Thus, the court reasoned, "the Riegels' claim, if successful, would result in state 'requirements' that differed from or added to those [federal] standards." *Id.* at 122.

The court viewed this case as "quite analogous to the hypothetical situation posed by Justice Breyer in his *Lohr* concurrence." *Id.*

Justice Breyer posited a federal MDA regulation that requires a 2-inch wire in a hearing aid. The wire, however, caused serious injury to a consumer, a known danger that could have been avoided if the manufacturer had used a shorter wire. Justice Breyer suggested that "an award by a jury persuaded by expert testimony that use of a more than 1-inch wire is negligent" would establish a requirement different than the MDA regulation.[4] Suggesting that the effects of such a jury verdict would be "identical" to a state agency regulation requiring a 1-inch wire, Justice Breyer questioned whether the state tort action should also be preempted. 518 US. at 504-05.

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[4] It is not indicated whether the hypothetical manufacturer alerted the FDA to the hazard presented by the 2-inch wire or whether the company sought to modify the regulation, matters that would be probative of due care under the circumstances.

For several reasons, the court below erred in relying on this hypothetical. First, as Justice Breyer himself indicated, § 360k is "highly ambiguous" and "Congress likely did not focus specifically upon the matter." *Id.* at 504-05.[5] Such a showing, he concluded, is not sufficient to surmount the presumption against preemption. *Id.* at 505. As the Court explained in connection with another statute expressly preempting state "requirements":

> Even if Dow had offered us a plausible alternative reading of § 136v(b) – indeed, even if its alternative were just as plausible as our reading of that text – we would nevertheless have a duty to accept the reading that disfavors pre-emption.

Bates, supra, 544 U.S. at 449.

Second, characterizing jury verdicts as state requirements does violence to the plain language of § 360k. A jury cannot comfortably be deemed a "State or political subdivision of a State." That usage is even less sensible in this case, where the role of the State would be played by a *federal* jury or *federal* judge rendering a verdict in this diversity case. Nor in common usage does a jury "establish or continue in effect" its verdict.

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[5] Given the lawmakers' overriding concern with FDA's premarketing authority, it is likely Congress saw no conflict with post-marketing liability. As one court has noted, "the legislative history recounts the difficulty the FDA experienced in its earlier attempts to keep dangerous medical devices out of the marketplace." "This attention to the regulation of medical devices *before* they reach the marketplace is consistent with" the absence of any expressed intent to affect manufacturers' liability after devices are sold. *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1378 (11th Cir. 1999) (emphasis in original).

Finally, and most importantly, the effects of state regulation and the effects of a jury verdict in a tort action are *not* identical. As trial lawyers are well aware, a jury verdict in favor of the plaintiff in a products liability case, requires nothing more than that the defendant compensate the plaintiff for the harm caused. See Philip H. Corboy and Todd A. Smith, *Federal Preemption of Product Liability Law: Federalism and the Theory of Implied Preemption,* 15 Am. J. Trial Adv. 435, 455-57 (1992); Ralph Nader and Joseph A. Page, *Automobile-Design Liability and Compliance With Federal Standards* 64 Geo. Wash. L. Rev. 415, 437-39 (1996).

A manufacturer may be influenced by a verdict to change the design of its product, but it is not required to do so. The product may already have been taken off the market or replaced by a newer, safer model. The manufacturer may decide to address the hazard by a warning or by a design change not considered by the jury. It could also rationally decide, balancing the probability of future serious harm against the cost of eliminating the risk, simply to compensate any future victims. Stephen Breyer, REGULATION AND ITS REFORM 175 (1982). In fact, most manufacturers sued for injury caused by their products do *not* change the product's design.[6]

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[6] Risk managers of Fortune 1000 corporations with actual product liability experience reported that as a result (1) over 35% had improved their product warnings and/or instructions; (2) over 30% had improved the safety of their designs and (3) 65% had established formal safety objectives. E. Patrick McGuire, The Impact of Product Liability 18 (Conference Bd. 1988), summarized in W. Page Keeton et al., Products Liability and Safety--Cases and Materials 1033-34 (2d ed. 1989).

As this Court recently stated, a jury verdict that creates an economic incentive to invest in safety does not impose a "requirement" as that term is used in a preemption provision:

> An occurrence that merely motivates an optional decision does not qualify as a requirement. . . .
>
> A requirement is a rule of law that must be obeyed; an event, such as a jury verdict, that merely motivates an optional decision is not a requirement.

Bates, 544 U.S. at 444-45.

The central concern of preemption is the exercise of power by the state or federal government. It is not concerned with the private choices by individuals and companies who remain free to select from variously attractive options. *See Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529, 1540-41 (D.C. Cir. 1984).

III. CONGRESS DID NOT INTEND TO ELIMINATE TRADITIONAL STATE TORT REMEDIES AND RELY SOLELY ON FDA REGULATIONS TO ENSURE THE SAFETY OF MEDICAL DEVICES.

The lower court erred in speculating that when Congress authorized the FDA to require premarket approval of medical devices, it intended to eliminate the longstanding reliance on post-marketing liability as a complementary means to achieve product safety.

A. Product Liability Plays a Distinct and Important Role Protecting Public Safety.

The court below attempted to distinguish this Court's decision in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), as limited to devices approved through premarketing notification (§ 510(k) process), rather

than through the more rigorous premarket approval ("PMA") process applicable to the catheter in this case.

In the court's view,

> [T]he PMA regime represented an entirely new approach of ensuring consumer safety through increased federal regulation and oversight. It is thus much less clear that the continuation of the previous tort remedies in the PMA context is consistent with the MDA's purpose.

451 F.3d 123.

The court offered no support for the proposition that Congress intended to pursue the goal of safety for the most potentially dangerous medical devices by eliminating common-law remedies for injured consumers, and relying on FDA regulation alone. Moreover, the court gave little heed to this Court's instruction to approach this question with "the general understanding of common-law damages actions" and their role in product safety. *Cipollone,* 505 U.S. at 521.

Mass production and mass marketing of consumer products has brought great progress and prosperity to Americans over the past century. But unreasonably dangerous products also pose grave risks of personal injury and death. Throughout this era, the United States has depended upon a two-pronged approach to ensuring product safety.

Governmental regulation assumes the marketplace cannot achieve the desired level of safety and instead imposes safety by decree. With respect to medical devices, the responsible agency is the Food and Drug Administration, first created in

1906 to regulate food safety and expanded in 1938 to cover drugs, medical devices and cosmetics.[7]

Product liability, on the other hand, allows the marketplace itself to provide the financial incentive for manufacturers to make their products safe. Product liability is an evolution of the fault principle adapted by common law courts to the modern marketplace, beginning with Justice Cardozo's landmark decision in *MacPherson v. Buick Motor Co.*, 111 N.E. 1050 (N.Y. 1916), more fully developed in *Greenman v. Yuba Power Products*, 377 P.2d 897 (Cal. 1963), and reaching its most widely adopted formulation in Restatement (Second) of Torts §402A (1965). *See generally*, Gary T. Schwartz, *The Vitality of Negligence and the Ethics of Strict Liability*, 15 Ga. L. Rev. 963 (1981).

Tort law has been called "law with a human face." Peter H. Schuck, *Introduction: The Context of the Controversy* 17, 21, in TORT LAW AND THE PUBLIC INTEREST (Peter H. Schuck ed., 1991). Its primary purpose is to compensate those who have been wrongfully injured. But product liability also plays an indirect role providing market incentives for safety. *See* John W. Wade, *On the Nature of Strict Tort Liability for Products*, 44 Miss. L.J. 825, 826 (1973).

It is well-accepted that in a marketplace in which all actors have perfect knowledge of risks, the

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[7] The FDA was originally called the Division of Chemistry, changed its name to the Food, Drug, and Insecticide Administration in 1927, and in 1930, adopted its current name. Sasha B. Rieders, *State Law Tort Claims and the FDA: Proposing a Consumer-Oriented Prescription in Medical Device Cases*, 25 Cardozo L. Rev. 1159, 1160 n.6 (2004).

market itself would provide the most efficient allocation of resources to produce reasonably safe products. Ronald H. Coase, *The Problem of Social Cost*, 3 J.L. & Econ. 1 (1960); Jon D. Hanson and Kyle D. Logue, *The First-Party Insurance Externality: an Economic Justification for Enterprise Liability*, 76 Cornell L Rev. 129, 161 (1990) (noting that the Coase Theorem is "well accepted"). That is, the market would favor products with the lowest sum of the cost of injuries plus the cost of injury prevention. *Id.*

Of course, real-world markets don't provide perfect consumer information. Manufacturers are able to "externalize" the injury costs of their products. Guido Calabresi, THE COSTS OF ACCIDENTS 70 (1970). That is, the manufacturer can force consumers, taxpayers, and society generally to subsidize his product by bearing part of the cost of the injuries it causes. This places the manufacturer who invests in safety at a competitive disadvantage, and unsafe products would tend to drive safer ones out of the marketplace. Product liability rules, by assessing risk retrospectively, compensate for imperfect consumer information. Steven P. Croley and Jon D. Hanson, *Rescuing the Revolution: The Revived Case for Enterprise Liability*, 91 Mich. L. Rev. 683, 707-08 (1993). See also W. Kip Viscusi, REFORMING PRODUCTS LIABILITY 66 (1991) ("The purpose of products liability is to fill the gaps left by market imperfections and to replicate the incentives that would have been generated had markets been functioning perfectly.")

In this way, "civil liability has a regulatory effect by promoting optimal deterrence – the taking of precautions and selection of activities that

minimize the sum of accident costs and accident avoidance costs." Kenneth S. Abraham, *The Insurance Effects of Regulation by Litigation*, in REGULATION THROUGH LITIGATION, at 212, 232 (W. Kip Viscusi ed. 2002). It is for the manufacturer to rationally decide whether it is cheaper to prevent future injuries by investing in safety precautions or to simply compensate future victims. *Id.*

Product liability duties therefore reflect a policy of making dangerous products pay their own way, that is, internalizing costs to achieve an efficient level of manufacturing operations. William M. Landes and Richard A. Posner, *The Positive Economic Theory of Tort Law*, 15 Ga. L. Rev. 851, 871-77 (1981); Richard C. Ausness, *Compensation For Smoking-Related Injuries: An Alternative to Strict Liability in Tort*, 46 Wayne L. Rev. 1085, 1140 (1990)("efficient allocation of resources is more likely if product prices reflect their actual social costs").

Viewed another way, the law requires the product's purchase price to reflect the costs of injuries so the "cheapest cost avoider" makes the most efficient allocation of resources. Guido Calabresi and Jon T. Hirschoff, *Toward a Test for Strict Liability in Torts*, Yale L.J. 1055, 1060 (1972) ("The question for the court reduces to a search for the cheapest cost avoider. . . . [i.e.] which of the parties to the accident is in the best position to make the cost-benefit analysis between accident costs and accident avoidance costs and to act on that decision once it is made."); *see also* Breyer, *supra*, at 175 (favoring rule "likely to place costs on the party best able to avoid them").

To the extent that preventing injury is cheaper than compensating the injured,

manufacturers have an economic incentive to make their products safer. *Id.* In this way, liability "is broadly consistent with an optimum investment in accident prevention by the enterprises subject to the standard." Richard A. Posner, *A Theory of Negligence*, 1 J. Legal Stud. 29, 30 (1972).

Safety by government regulation is a much different regime. It is premised on the belief that the marketplace cannot achieve the level of safety society demands. Croley and Hansen, *supra* at 736. Regulators therefore command manufacturers to do that which they would not do voluntarily. In many ways, regulation and liability are polar opposites. Administrative regulations are prospective; liability assesses past conduct. Regulations prescribe specific design or performance standards; a liability verdict assesses whether a manufacturer met a duty of care under the circumstances of a particular case. Regulatory penalties are imposed to enforce compliance; a liability verdict is measured to compensate for wrongful death and injury. *See* Steven Shavell, *Liability for Harm Versus Regulation of Safety*, 13 J. Legal Studies 357, 359 (1984) (explaining that administrative regulation is a centralized system of government control, while tort law is essentially a market-based system).

In his classic exposition, Judge Calabresi contrasts the indirect influence exerted on the market by tort law ("general deterrence") with governmental regulatory mandates ("specific deterrence"). Calabresi, THE COSTS OF ACCIDENTS, *supra*, at 68-129. As one scholar summarized:

> [U]nder a general deterrence regime, manufacturers, not government officials, make decisions about product safety. . . . In contrast,

> specific deterrence mandates a particular choice determined by the legislature or an administrative agency. *It is a raw exercise of state power.*

Richard C. Ausness, *Cigarette Company Liability: Preemption, Public Policy, and Alternative Compensation Systems*, 39 Syracuse L. Rev. 897, 927 (1988) (emphasis added). It is the exercise of government power, not the private decisions of individuals, that is preemption's concern.

For this reason, this Court has consistently held that preemption of direct regulation by administrative agencies does not necessarily include the indirect influence of tort awards:

> The effects of *direct* regulation on the operation of federal projects are significantly more intrusive than the *incidental* regulatory effects of such an additional award provision. . . . We believe Congress may reasonably determine that *incidental regulatory pressure is acceptable, whereas direct regulatory authority is not.*

Goodyear Atomic Corp. v. Miller, 486 U.S. 174, 185 (1988) (emphasis added). *See also English v. General Electric Co.*, 496 U.S. 72, 85 (1990) (The effect of tort awards "is neither direct nor substantial enough to place petitioner's claim in the preempted field" with administrative regulations); *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 258 (1984) (vesting federal agency "with exclusive regulatory authority over the safety aspects of nuclear development" was not inconsistent with allowing plaintiffs to recover for injuries caused by nuclear hazards).

Justice Blackmun later described the import of these decisions: "The level of choice that a defendant retains in shaping its own behavior distinguishes the

indirect regulatory impact of the common law from positive enactments such as statutes and administrative regulations." *Cipollone, supra*, 505 U.S. at 536-37 (Blackmun, J., concurring in part, dissenting in part).

B. Congress Would Not Have Intended To Ensure the Safety of the Most Potentially Dangerous Devices Through Regulation Alone.

As noted earlier, the Court of Appeals saw the PMA regime as

> an entirely new approach of ensuring consumer safety through increased federal regulation and oversight. It is thus much less clear that the continuation of the previous tort remedies in the PMA context is consistent with the MDA's purpose.

451 F.3d 123.

At the outset, it must be noted that the court's standard – whether tort remedies are consistent with the statute's purpose – may be appropriate for implied "conflict" preemption. *E.g.*, *Geier*, 529 U.S. at 873 (implied preemption where state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress"). However, a court's role in construing an express preemption provision is much more limited. The lower court's assertion is bereft of any authority indicating that Congress intended to abolish tort remedies and rely solely on FDA regulation.

The more appropriate starting place, as this Court has instructed, is the assumption that Congress was "familiar with common-law principles . . . recognized in ordinary tort litigation [and] 'likely

intended these common-law principles to obtain, absent specific provisions to the contrary.'" *Will v. Michigan Dept. of State Police*, 491 U.S. 58, 67 (1989), quoting *City of Newport v. Fact Concerts, Inc.*, 453 U.S. 247, 258 (1981).

One important common-law principle is that the two prongs of America's approach to product safety – regulation and liability – are complementary and not mutually exclusive. *See, e.g., CSX Transportation, Inc. v. Easterwood*, 507 U.S. 658, 668 (1993) (state "negligence liability could just as easily complement" railroad crossing regulations under the Federal Railroad Safety Act); *Silkwood* at 264 (Blackmun, J., dissenting) (Tort damages "complement the federal regulatory standards, and are an implicit part of the federal regulatory scheme."); *Larsen v. General Motors Corp.*, 391 F.2d 495, 506 (8th Cir. 1968) ("It is apparent that the National Traffic Safety Act is intended to be supplementary of and in addition to the common law of negligence and product liability."); *Graham v. Wyeth Labs.*, 666 F. Supp. 1483, 1493 (D. Kan. 1987) (state tort actions actually enhance the goal of the National Childhood Vaccine Injury Act of optimum vaccine safety).

As the former FDA Chief Counsel has written, "FDA product approval and state tort liability usually operate independently, each providing a significant, yet distinct level of consumer protection." Margaret J. Porter, *The Lohr Decision: FDA Perspective and Position*, 52 Food & Drug L.J. 7, 11 (1997). *See also* 1 American Law Institute, REPORTERS' STUDY: ENTERPRISE RESPONSIBILITY FOR PERSONAL INJURY, 50 (1991); Steven Shavell, *Liability for Harm Versus Regulation of Safety*, 13 J.

Legal Studies 357 (1984); Susan Rose-Ackerman, *Tort Law in the Regulatory State*, in TORT LAW AND THE PUBLIC INTEREST 82-83 (Peter H. Schuck ed., 1991).

Courts have described this complementary relationship by stating that federal regulatory standards are "a floor, not a ceiling." *See, e.g., Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1542-43 (D.C. Cir. 1984); *Dorsey v. Honda Motor Co.*, 655 F.2d 650, 656 (5th Cir. 1981); *see generally*, Clarence Morris, *The Role of Administrative Safety Measures in Negligence Actions*, 28 Tex. L. Rev. 143, 157-66 (1949).

> For a hundred years courts have considered axiomatic the common law principle that compliance with safety regulations is evidence for the jury that the defendant exercised due care. At the same time, such compliance generally 'does not prevent a finding of negligence where a reasonable man would take additional precautions.'

Paul Deuffert, *The Role of Regulatory Compliance in Tort Actions*, 26 Harv. J. on Legis. 175, 175 (1989), quoting Restatement (Second) of Torts § 288(C) (1965).[8]

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[8] See also Restatement (Third) of Torts: Product Liability § 4 (1998):

> (b) a product's compliance with an applicable product safety statute or administrative regulation is properly considered in determining whether the product is defective with respect to the risks sought to be reduced by the statute or regulation, but such compliance does not preclude as a matter of law a finding of product defect.

In enacting the MDA, Congress gave no indication of departing from that historical position. Certainly Congress was under no illusion that federal regulators are so effective that they need no assistance from common law liability.

Federal administrative agencies are subject to budgetary constraints, political pressures, and simple human shortcomings.[9]

> Federal administrative agencies have been subjected to an increasing barrage of criticism emanating from a variety of philosophical and political positions. Economists are concerned with the inefficiency, waste, and shortages they see caused by certain kinds of regulation. . . . Consumer groups complain that regulation is ineffective.

Stephen G. Breyer & Richard B. Stewart, ADMINISTRATIVE LAW AND REGULATORY POLICY 130-31 (2d ed. 1985). See also *See* 1 American Law Institute, REPORTERS' STUDY: ENTERPRISE RESPONSIBILITY FOR PERSONAL INJURY 47-49 (1991) (the consensus of empirical studies is that "although compliance with regulatory standards has exacted substantial costs from business, the payoff in injury prevention has been disappointingly modest.").

Certainly there is no support for the notion that Congress relied entirely upon the FDA's ability to ensure the safety of the large number of medical devices entering the marketplace. Adler and Mann,

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[9] It has been pointed out that the Titanic set sail in compliance with governmental regulations setting minimum requirements for lifeboats, though they could accommodate only about half the people on board. *Geier v. American Honda Motor Co., Inc.*, 529 U.S. 861, 903 n.19 (2000) (Stevens, J., dissenting).

supra, at 942. "To the contrary, Congress has repeatedly identified shortcomings in FDA's regulation of medical devices." *Id.* at n.191 (listing congressional investigative reports). Daniel W. Sigelman, *Turning the Tables on Drug Companies: Exposing Deficiencies in FDA Regulation*, 30 Trial 72 (1994) ("Implicit in the 'FDA approval defense' is the assumption that agency regulation protects the public from the dangers of marketed drugs. Congressional oversight of FDA's performance, however, challenges the validity of this assumption.").

One example stems from the Dalkon Shield scandal itself. The dishonesty of manufacturer A.H. Robins Co., its refusal to conduct adequate testing of its IUD, its disregard of adverse reports from physicians, and its destruction of evidence were not uncovered by the FDA. "To the contrary, the FDA turned its attention away from the Dalkon Shield after negotiating a 'voluntary' suspension of sales in the United States." Instead, that evidence was uncovered in the course of product liability litigation. Adler & Mann, *supra*, at 944.

As one court pointedly remarked, "It would have been inconsistent for the same Congress that enacted these sweeping reforms, intending to make a potentially dangerous industry safer for patients by blocking the admission of defective devices to the market, then to preempt product liability suits when those devices caused injury." *Goodlin*, *supra*, 167 F.3d at 1378.

Moreover, this Court has for more than two centuries held that "[o]ne of the first duties of government" is to safeguard "the right of every individual to claim the protection of the laws,

whenever he receives an injury." *Marbury v. Madison*, 5 U.S. (1 Cranch) 137, 163 (1803). Under the Due Process Clause, it is "the duty of every State to provide, in the administration of justice, for the redress of private wrongs." *Missouri Pacific Ry. Co. v. Humes*, 115 U.S. 512, 521 (1885). Indeed, the right to recover damages for wrongful personal injury is among the "absolute rights of individuals" that the Founders intended to guarantee to all Americans. *Ingraham v. Wright*, 430 U.S. 651, 675 (1977).

For Congress to have eliminated that right for those injured by unreasonably dangerous medical devices, without a mention of such a drastic step, would have been "spectacularly odd." *Lohr*, 518 U.S. at 491 (plurality opinion).

CONCLUSION

For the above reasons, the decision of the court of appeals below should be reversed.

Respectfully submitted,

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